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APPLICATION NO.:	U# FILING DATE / 26/97	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. U 274-30-360
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EXAMINER  
DEAN, R

ART UNIT	PAPER NUMBER
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DATE MAILED: 01/11/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/935,087</b>	Applicant(s) <b>Tsuneji Suzuki et al</b>
	Examiner <b>Rita Desai</b>	Group Art Unit <b>1612</b>

Responsive to communication(s) filed on Oct 23, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) 28-30 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-27, 31, and 32 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan # 258863/1996 on 09/30/96. It is noted, that neither a priority document or a certified translation has been filed. Therefore the benefit based on foreign priority has not been granted.

2. ***Restriction/Election***

As presented,

Invention I, Claims 1-27, 31 and 32 drawn to a benzamide compound.

Invention II, Claims 28-30 drawn to an anilide compound.

Claims as grouped above are deemed to be different inventions under the provisions of MPEP section 806.04.

The anilide is viewed as being an independent species under the genus identified by compounds of claim 1. The inventions are considered to be independent in that each may be formed separately from the other and are not viewed as being dependent upon each other.

This application contains claims directed to the following patentably distinct species of the claimed Invention I, ie where A is a Phenyl group, A is a Pyridyl group or, A is any other Heterocyclic group other than a pyridyl group, each of which may be further optionally

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substituted by various groups selected from amino group, halogen group , cyano group, nitro group, alkyl group having 1-4 carbon atoms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 is the generic claim of Invention I.

This application also contains claims directed to the following patentably distinct species of the claimed Invention II, ie where A is a Phenyl group, A is a Pyridyl group or, A is any other Heterocyclic group other than a pyridyl group, each of which may be further optionally substituted by various groups selected from amino group, halogen group , cyano group, nitro group, alkyl group having 1-4 carbon atoms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 28, is the generic claim of Invention II.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Unpatentability of the Invention I compounds would not necessarily imply unpatentability of Invention II compounds, because the compounds are so divergent that a reference providing a 35 U.S.C.102(b) rejection on a member of one invention would not render a member of the other invention obvious under 35 U.S.C. 103.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Robert Mukai on 12/08/98, Invention I and a species where A is a pyridyl group was elected with traverse. Affirmation of this election plus <sup>the</sup> ~~an~~ election of species must be made by the applicant in replying to this office action.

3.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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**3a.** Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for colon cancer, does not reasonably provide enablement for all types of cancer . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope is broader than the description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**3b.** Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an hybrid type claim, because it is ambiguous and cannot be distinguished as an duplicate claim for the drug or a method claim of using the drug.

**4. *Claim Rejections - 35 USC § 102***

**4a.** (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-27 are rejected under 35 U.S.C. 102(a) as being anticipated by El-Sayed et al WO97/24328.

El Sayed '328 discloses compounds of general formula I page 175, specifically the 4th and 5th compound on page 194.

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The R5 and R7 groups of the instant compounds can be hydrogen or optionally substituted 1-4 carbon alkyl groups page 5 lines 2 and 10 of the specifications. In the specifications on page 10 line 2, the optionally substituted group can be a phenyl group. With these options the compounds are anticipated by El-Sayed'328.

**4b.** (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-27 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by El-Sayed et al WO97/24328.

El-Sayed Et al WO97/24328 is in the national stage with a filing dated of 16 Dec. 1996. The filing date of the instant application is 26 Sept. 1997, thus El-Sayed was filed in the United States before the invention therof and hence the instant claims are rejected under 35 U.S.C. 102(e).

The claims of El-Sayed '328 and the instant claims have overlapping subject matter.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Desai whose telephone number is (703) -305-1868. The examiner can normally be reached on Monday to Friday from 8.00 am to 4.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the supervisor, Mr. John Kight, can be reached on (703) 308-0204.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235 .

R.D.

5th Jan. 1999.



JOHN KIGHT  
SUPERVISORY PATENT EXAMINER  
GROUP 1200